

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1-10 are currently being examined. Claims 11-13, 15, and 17-19 are withdrawn.

Summary of the Office Action

Claims 1-10 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Reconsideration of the pending claims is hereby requested.

Discussion of the Enablement Rejection

The Examiner acknowledges that the specification enables isolated and purified poecillastrin A. However, the Office contends that the claims are directed to a compound of formula (I), and there “is no guidance or working examples for the rest of the compounds of formula (I)” other than poecillastrin A (Office Action, page 2, item (4)). This rejection is respectfully traversed.

Contrary to the Office’s contention, the specification explains to the skilled artisan various methods of making compounds of formula (I) without undue experimentation. More particularly, the specification describes that the compounds of formula (I) can be made by chemically modifying various groups (e.g., page 7, line 16, to page 12, line 13). Synthetic methods of preparing compounds of formula (I) by direct methods or modification of poecillastrin A are described at, for example, page 12, line 14, to page 13, line 31. The specification also describes the isolation and purification of certain compounds of the present invention, when obtained as solvent extracts from marine sponges (page 29, line 31, to page 31, line 27). See the enclosed Declaration under 37 C.F.R. § 1.132 of Dr. Michael R. Boyd. Definitive proofs of the structure of the isolated compounds can be determined based on the methods described at, for example, page 31, lines 28-32. See the enclosed Declaration under 37 C.F.R. § 1.132 of Dr. Michael R. Boyd.

The specification also teaches one of ordinary skill in the art how to use the invention. Methods for determining the vacuolar-type (H⁺)-ATPase inhibitory activity and cytotoxicity for compounds of formula (I) are described in the specification at, for example, page 19, line

6, to page 29, line 30. See the enclosed Declaration under 37 C.F.R. § 1.132 of Dr. Michael R. Boyd. Exemplary conditions that are susceptible to prevention or treatment by a compound of formula (I) are described in the specification at, for example, page 16, line 27, to page 18, line 7. Formulations of compounds of formula (I) are described in the specification at, for example, page 14, line 4, to page 16, line 13 and page 18, lines 18, to page 19, line 5, and includes modes of administration, carriers, and concentrations. Suitable doses are described in the specification at, for example, page 16, lines 14-26.

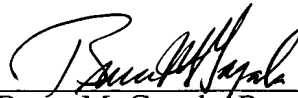
Thus, the present specification provides considerable direction and guidance for how to make and use the compounds of formula (I). In addition, compounds of formula (I) have been shown to have vacuolar-type (H⁺)-ATPase inhibitory activity and cytotoxicity (see, e.g., page 19, line 6 through page 29, line 39 and Examples 3-6), and all of the methods needed to practice the invention are explained in the specification and/or are considered well known in the art. See the enclosed Declaration under 37 C.F.R. § 1.132 of Dr. Michael R. Boyd. Therefore, a person skilled in the art would be able to make and use the invention as a whole without undue experimentation.

In view of the foregoing, claims 1-10 are enabled by the specification, and this rejection should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Date: October 3, 2006